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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/879,217	06/13/2001	Kathleen Danenberg	11220/129	6207
23838	7590	06/15/2004	EXAMINER	
KENYON & KENYON 1500 K STREET, N.W., SUITE 700 WASHINGTON, DC 20005			FREDMAN, JEFFREY NORMAN	
			ART UNIT	PAPER NUMBER

1637

DATE MAILED: 06/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action

Application No.

09/879,217

Applicant(s)

DANENBERG, KATHLEEN6

Examiner

Jeffrey Fredman

Art Unit

1637

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 01 June 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.
- b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
- ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on June 1, 2004. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see Note below);
- (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____

3. ☐ Applicant's reply has overcome the following rejection(s): _____.
4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____

Claim(s) objected to: _____

Claim(s) rejected: 12-14, 16, 23-25, 27-29 and 31-34.

Claim(s) withdrawn from consideration: _____

8. ☐ The drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
10. ☐ Other: _____

Jeffrey Fredman
Primary Examiner
Art Unit: 1637

Continuation of 5. does NOT place the application in condition for allowance because: Applicant argues that the deletion of the term "about" overcomes the rejection because the prior art does not teach the precise temperatures or time frames selected by Applicant. This selection simply represents routine optimization which is prima facie obvious. An ordinary practitioner would have recognized that the results optimizable variable of time of reaction, the most commonly varied element in any experiment, could be adjusted to maximize the desired results. As noted in *In re Aller*, 105 USPQ 233 at 235, "More particularly, where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." Routine optimization is not considered inventive and no evidence has been presented that the selection of specific temperatures for amplification was other than routine, that the products resulting from the optimization have any unexpected properties, or that the results should be considered unexpected in any way as compared to the closest prior art.

Applicant then argues that Wilhauck teaches away from the use of internal controls such as Beta-actin. For claims not including this limitation, this argument is irrelevant since the Wilhauck clearly suggests the use of internal controls in a clear way as discussed in the rejection. For claims drawn to B-actin, an additional reference, Johnston is included, who teaches the use of B-actin as an internal control for the specific enzyme involved with 5-fluorouracil, so there is a specific suggestion by Johnston of B-actin as a control when measuring 5-fluorouracil type enzymes. This overcomes any more generic teaching away of B-actin of Wilhauck.

Applicant traverses the reasonable expectation of success provided by Buck. Here, Applicant attempts to use argument to neutralize evidence. Applicant's argument is not persuasive since Buck shows that all primers are expected to be equivalent. Applicant has no counter evidence, only an argument that Buck represents one particular situation. That is of necessity, since no one can test everything in the whole world. Using the only evidence of record, the data provided by Buck, the evidence as a whole shows a more than reasonable expectation of success.

Finally, Applicant argues the motivation to combine. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case specific motivation is provided in the rejections.